

## CLAIMS

What is claimed is:

1. An intradermal needle assembly for use with a prefillable container having a reservoir capable of storing a substance for injection into the skin of an animal
  - 5 comprising:
    - a hub portion being attachable to the prefillable container storing the substance;
    - a needle cannula supported by said hub portion and having a forward tip extending away from said hub portion; and
    - a limiter portion surrounding said needle cannula and extending away from said
  - 10 hub portion toward said forward tip of said needle cannula, said limiter including a generally flat skin engaging surface extending in a plane generally perpendicular to an axis of said needle cannula and adapted to be received against the skin of the animal to administer an intradermal injection of the substance, said needle forward tip extending beyond said skin engaging surface a distance approximately 0.5 mm to 3.0 mm wherein
  - 15 said limiter portion limits penetration of the needle into the dermis layer of skin of the animal so that the vaccine is injected into the dermis layer of the animal.
2. An assembly as set forth in claim 1 wherein said plane is generally perpendicular to said axis of said needle cannula within about fifteen degrees.
- 20 3. An assembly as set forth in claim 1 wherein said plane is generally perpendicular to said axis of said needle cannula within about five degrees.

4. An assembly as set forth in claim 1 wherein said hub portion and said limiter portion are formed as separate pieces.

5. An assembly as set forth in claim 4 wherein said limiter portion defines an inner cavity receiving at least a portion of said hub and including an abutment engaging a corresponding structure on said hub portion thereby limiting the length of said needle cannula extending beyond said skin engaging surface.

6. An assembly as set forth in claim 5 wherein said hub portion includes a throat for receiving the prefillable container.

7. An assembly as set forth in claim 6 wherein said needle cannula is fixedly attached to said hub portion.

8. An assembly as set forth in claim 7 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

9. An assembly as set forth in claim 8 wherein said adhesive comprises an epoxy curable with ultra violet light.

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10. An assembly as set forth in claim 9 wherein said limiter portion includes a plurality of snaps engaging said hub portion thereby fixedly attaching said hub portion to said limiter portion.

11. An assembly as set forth in claim 1 wherein said limiter portion and said hub portion are integrally formed as a single component.

5           12. An assembly as set forth in claim 11 wherein said needle cannula is fixedly attached to said hub portion of said single component behind said skin engaging surface of said limiter portion.

10           13. An assembly as set forth in claim 12 wherein said hub portion includes a throat for receiving the prefillable container.

            14. An assembly as set forth in claim 13 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

15           15. An assembly as set forth in claim 14 wherein said adhesive comprises an epoxy curable with ultra violet light.

            16. An assembly as set forth in claim 1 wherein said skin engaging surface comprises a rigid polymer having an elastomeric central area with said needle cannula  
20           extending therethrough.

            17. An assembly as set forth in claim 1 wherein said substance includes an influenza vaccine.

18. An assembly as set forth in claim 1 wherein said needle assembly is attachable to a prefillable container with a Leur fit.

5 19. An assembly as set forth in claim 1 further including a sleeve circumscribing said limiter and being slidable for shielding said forward tip subsequent to administering an intradermal injection.

10 20. An assembly as set forth in claim 19 wherein said limiter includes at least one ramp allowing said limiter to be moved toward said forward tip and preventing said limiter from being moved away from said forward tip upon shielding said forward tip.

21. An assembly as set forth in claim 20 further including a tip cap removably affixed to said skin engaging surface and having said forward tip received therein.

15 22. An assembly as set forth in claim 1 wherein said limiter includes a needle plunger slidably received thereby and being oriented generally perpendicular to said axis of said needle cannula within about fifteen degrees.

20 23. An assembly as set forth in claim 22 wherein said needle plunger is depressable thereby bending said needle cannula and retracting said needle cannula into said limiter for shielding said forward tip subsequent to administering an injection.

24. An assembly as set forth in claim 1 further including a forward cap being matable to a rearward cap wherein said caps enclose said needle assembly therebetween.

25. An assembly as set forth in claim 24 wherein said forward cap and said  
5 rearward cap form a sterile enclosure for storing said needle assembly.

26. An assembly as set forth in claim 1 wherein said skin engaging surface includes an outer diameter of at least 5 mm.

27. A method of using the assembly of claim 1, comprising:  
a) providing the assembly of claim 1;  
b) engaging the skin engaging surface with a skin of a patient;  
c) actuating the actuator to move the needle assembly from the retracted position to the extended position;  
d) withdrawing the needle assembly from the skin of the patient;  
e) retracting the needle assembly to the retracted position;  
f) separating the needle assembly from the skin of the patient;  
g) separating the needle assembly from the skin of the patient;  
h) separating the needle assembly from the skin of the patient;  
i) separating the needle assembly from the skin of the patient;  
j) separating the needle assembly from the skin of the patient;  
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w) separating the needle assembly from the skin of the patient;  
x) separating the needle assembly from the skin of the patient;  
y) separating the needle assembly from the skin of the patient;  
z) separating the needle assembly from the skin of the patient;

27. An intradermal needle assembly for use with a prefillable container having a reservoir capable of storing a substance for injection into the skin of an animal comprising:

- 5 a hub portion having a throat for receiving the prefillable container;
- a needle cannula being supported by said hub portion and having a forward tip extending away from said hub portion;
- a limiter portion surrounding said hub portion and said needle cannula and extending away from said hub portion toward said forward tip of said needle, said limiter
- 10 portion including a generally flat skin engaging surface extending in a plane generally perpendicular to an axis of said needle cannula and being adapted to be received against the skin of an animal to receive an intradermal injection of a vaccine, and said forward tip extending beyond the skin engaging surface from approximately 0.5 mm to approximately 3.0 mm wherein the limiter portion limits penetration of said needle
- 15 cannula into the dermis layer of the skin of the animal thereby injecting the substance into the dermis layer of the animal.

28. An assembly as set forth in claim 27 wherein said plane is generally perpendicular to said axis of said needle cannula within about fifteen degrees.

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29. An assembly as set forth in claim 27 wherein said plane is generally perpendicular to said axis of said needle cannula within about five degrees.

30. An assembly as set forth in claim 27 wherein said hub portion and said limiter portion are formed as separate pieces.

31. An assembly as set forth in claim 30 wherein said limiter portion defines an inner cavity receiving at least a portion of said hub and including an abutment engaging a corresponding structure on said hub portion thereby limiting the length of said needle cannula extending beyond said skin engaging surface.

32. An assembly as set forth in claim 31 wherein said needle cannula is fixedly attached to said hub portion.

33. An assembly as set forth in claim 32 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

34. An assembly as set forth in claim 33 wherein said adhesive comprises an epoxy curable with ultra violet light.

35. An assembly as set forth in claim 27 wherein said limiter portion includes a plurality of snaps engaging said hub portion thereby fixedly attaching said hub portion to said limiter portion.

36. An assembly as set forth in claim 27 wherein said limiter portion and said hub portion are integrally formed as a single component.

37. An assembly as set forth in claim 36 wherein said needle cannula is fixedly attached to said hub portion of said single component behind said skin engaging surface of said limiter portion.

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38. An assembly as set forth in claim 37 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

39. An assembly as set forth in claim 27 wherein said adhesive comprises an epoxy curable with ultra violet light.

40. An assembly as set forth in claim 27 wherein said skin engaging surface comprises a rigid polymer having an elastomeric central area with said needle cannula extending therethrough.

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41. An assembly as set forth in claim 27 wherein said substance includes an influenza vaccine.

42. An assembly as set forth in claim 27 wherein said needle assembly is attachable to a prefillable container with a Leur fit.

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43. An assembly as set forth in claim 27 further including a sleeve circumscribing said limiter and being slidable for shielding said forward tip subsequent to administering an intradermal injection.

5           44. An assembly as set forth in claim 43 wherein said limiter includes at least one ramp allowing said limiter to be moved toward said forward tip and preventing said limiter from being moved away from said forward tip upon shielding said forward tip.

10           45. An assembly as set forth in claim 44 further including a tip cap removably affixed to said skin engaging surface and having said forward tip received therein.

15           46. An assembly as set forth in claim 27 wherein said limiter includes a needle plunger slidably received thereby and being oriented generally perpendicular to said axis of said needle cannula.

20           47. An assembly as set forth in claim 46 wherein said needle plunger is depressable thereby bending said needle cannula and retracting said needle cannula into said limiter for shielding said forward tip subsequent to administering an injection.

25           48. An assembly as set forth in claim 27 further including a forward cap being matable to a rearward cap wherein said caps enclose said needle assembly therebetween.

49. An assembly as set forth in claim 48 wherein said forward cap and said rearward cap form a sterile enclosure for storing said needle assembly.

50. An assembly as set forth in claim 27 wherein said skin engaging surface  
5 includes an outer diameter of at least 5 mm.

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51. An intradermal needle assembly attachable to a prefillable container having a reservoir adapted to contain a substance for use in intradermally injecting vaccines into the skin of an animal, comprising:

5 a needle cannula affixed to a hub portion and being in fluid communication with the outlet port, the needle having a forward tip that is adapted to penetrate the skin of an animal; and

10 a limiter surrounding said needle cannula and having a generally flat skin engaging surface extending in a plane ranging between five and fifteen degrees from perpendicular to an axis of said needle cannula and being adapted to be placed against the skin of the animal to administer an intradermal injection of the substance, said needle forward tip extending away from said skin engaging surface from approximately 0.5 mm to approximately 3.0 mm such that said limiter limits penetration of said forward tip into the dermis layer of the skin of an animal so that the substance is injected into the dermis layer of the skin.

15 52. An assembly as set forth in claim 51 wherein said hub portion and said limiter portion are formed as separate pieces.

20 53. An assembly as set forth in claim 51 wherein said limiter portion defines an inner cavity receiving at least a portion of said hub and including an abutment engaging a corresponding structure on said hub portion thereby limiting the length of said needle cannula extending beyond said skin engaging surface.

54. An assembly as set forth in claim 51 wherein said hub portion includes a throat for receiving the prefillable container.

5 55. An assembly as set forth in claim 51 wherein said needle cannula is fixedly attached to said hub portion.

56. An assembly as set forth in claim 55 wherein said needle cannula is fixedly attached to said hub portion with an adhesive.

10 57. An assembly as set forth in claim 56 wherein said adhesive comprises an epoxy curable with ultra violet light.

15 58. An assembly as set forth in claim 57 wherein said limiter portion includes a plurality of snaps engaging said hub portion thereby fixedly attaching said hub portion to said limiter portion.

59. An assembly as set forth in claim 51 wherein said limiter portion and said hub portion are integrally formed as a single component.

20 60. An assembly as set forth in claim 59 wherein said needle cannula is fixedly attached to said hub portion of said single component behind said skin engaging surface of said limiter portion.

61. An assembly as set forth in claim 51 wherein said hub portion includes a throat for receiving the prefillable container.

62. An assembly as set forth in claim 61 wherein said needle cannula is fixedly  
5 attached to said hub portion with an adhesive.

63. An assembly as set forth in claim 62 wherein said adhesive comprises an epoxy curable with ultra violet light.

10 64. An assembly as set forth in claim 51 wherein said substance includes an influenza vaccine.

65. An assembly as set forth in claim 51 wherein said needle assembly is attachable to a prefillable container with a Leur fit.

15 66. An assembly as set forth in claim 51 further including a sleeve circumscribing said limiter and being slidable for shielding said forward tip subsequent to administering an intradermal injection.

20 67. An assembly as set forth in claim 51 wherein said limiter includes at least one ramp allowing said limiter to be moved toward said forward tip and preventing said limiter from being moved away from said forward tip upon shielding said forward tip.

68. An assembly as set forth in claim 67 further including a tip cap removably affixed to said skin engaging surface and having said forward tip received therein.

69. An assembly as set forth in claim 51 wherein said limiter includes a needle plunger slidably received thereby and being oriented generally perpendicular to said axis of said needle cannula.

70. An assembly as set forth in claim 69 wherein said needle plunger is depressable thereby bending said needle cannula and retracting said needle cannula into said limiter for shielding said forward tip subsequent to administering an injection.

71. An assembly as set forth in claim 51 further including a forward cap being matable to a rearward cap wherein said caps enclose said needle assembly therebetween.

72. An assembly as set forth in claim 71 wherein said forward cap and said rearward cap form a sterile enclosure for storing said needle assembly.

73. An assembly as set forth in claim 51 wherein said skin engaging surface includes an outer diameter of at least 5 mm.

74. An intradermal needle assembly for use with a prefillable container having a reservoir capable of storing a substance for injection into the skin of an animal comprising:

- a hub portion being attachable to the prefillable container storing the substance;
- 5 a needle cannula supported by said hub portion and having a forward tip extending away from said hub portion;
- a limiter portion surrounding said needle cannula and extending away from said hub portion toward said forward tip of said needle cannula, said limiter including a generally flat skin engaging surface extending in a plane generally perpendicular to an
- 10 axis of said needle cannula and adapted to be received against the skin of the animal to administer an intradermal injection of the substance, said needle forward tip extending beyond said skin engaging surface a distance approximately 0.5 mm to 3.0 mm wherein said limiter portion limits penetration of the needle into the dermis layer of skin of the animal so that the vaccine is injected into the dermis layer of the animal; and
- 15 an enclosure means for concealing said needle cannula following injection.

75. An assembly as set forth in claim 74 wherein said enclosure means comprises said limiter being slideably disposed about said needle cannula and having at least a first position and a second position, said first position exposing said forward tip
- 20 of said needle cannula and said second position concealing said forward tip of said needle cannula.

76. An assembly as set forth in claim 75 wherein said limiter defines at least one slot oriented generally parallel to said needle cannula and having a protuberance disposed on one side thereof.

5           77. An assembly as set forth in claim 76 further comprising a hub supporting said needle cannula and said hub including at least one locking finger and at least one stop, said at least one locking finger being cantilevered away from said forward tip and said at least one stop being cantilevered toward said forward tip.

10           78. An assembly as set forth in claim 77 wherein said at least one locking finger includes a tab received by said slot disposed in said limiter.

15           79. An assembly as set forth in claim 78 wherein said tab is snappable over said protuberance for moving said limiter from said first position to said second position.

20           80. An assembly as set forth in claim 79 wherein said protuberance is disposed between said tab and said at least one stop when said limiter is located in said first position.

25           81. An assembly as set forth in claim 80 wherein said limiter includes a catch engaging said at least one stop when said limiter is in said second position thereby preventing said limiter from being moved into said first position from said second position.



82. An assembly as set forth in claim 74 wherein said limiter comprises a non-elastomeric polymer.

5           83. An assembly as set forth in claim 82 wherein said skin engaging surface comprises an elastomeric polymer being circumscribed by said non-elastomeric polymer.

84. An assembly as set forth in claim 83 wherein said elastomeric polymer is pierced by said needle cannula when said limiter is mated to said hub portion.

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85. An assembly as set forth in claim 84 wherein said forward end includes a beveled tip ranging in length between approximately 0.8 mm and 1.0 mm.

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86. An assembly as set forth in claim 85 wherein said forward end includes a beveled tip having a length of approximately 0.9 mm in length.

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87. An assembly as set forth in claim 74 wherein said enclosure means comprises a needle plunger inserted through said limiter and being depressable for bending said needle cannula thereby retracting said needle cannula into said limiter.

88. An assembly as set forth in claim 87 wherein said needle plunger is oriented generally perpendicular to said needle cannula.

89. An assembly as set forth in claim 74 including a cap attachable to said skin engaging surface for concealing said forward tip.

90. An assembly as set forth in claim 89 wherein said cap comprises an elastomer  
5 and said forward tip is inserted into said elastomer thereby sealing said needle cannula and preventing said substance from leaking from said prefillable container through said cannula.

91. An assembly as set forth in claim 74, wherein said enclosure means comprises  
10 a tubular shield extendable from a retracted position to an extended position enclosing said needle cannula.

92. An assembly as set forth in claim 74, wherein said needle forward tip extends  
beyond said skin engaging surface about 1.0 to 2.0 mm.

93. An assembly as set forth in claim 74, wherein said needle forward tip extends  
beyond said skin engaging surface  $1.5 \text{ mm} \pm 0.2$  to 0.3 mm.

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